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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/827,190 | 04/19/2004 | Gary J. Calton | Nut-0001b | 2323 |

7590 08/28/2007

Beverly J. Artale
Suite 001
3826 Sunflower Circle
Mitchellville, MD 20721

| EXAMINER | |
|---|---|
| MAEWALL, SNIGDHA | |
| ART UNIT | PAPER NUMBER |
| 1615 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 08/28/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/827,190 | CALTON ET AL. | |
| | Examiner | Art Unit | |
| | Snigdha Maewall | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3 and 5-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Summary*

1. Receipt of Applicants Amended Claims with proper renumbering filed on 06/15/2007 is acknowledged. Claim **4** has been cancelled. In view of the renumbering of the claims, the updated status of the pending claims has been changed from the originally filed claims. Claim **55** does not exist any more; claims **20 and 47** have been amended. **Accordingly, claims 1-3 and 5-54 are pending in this application and claims 1-3 and 5-54 will be prosecuted on the merits.**

In view of Applicants Amendments, the rejections made under 35 USC 112 have been withdrawn.

**The following rejections of record are maintained.**

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3.Claims 1-3, 5-6, 11-14, 16-23, 28-31, 33-36, 44-47, 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakashima et. al. (U.S. Patent No. 4645662 A).

Nakashima et. al teaches:

The oral composition in the form of toothpaste, toothpowder, ointment (liquid or gel) and mouthwash in order to alleviate dental sensitivity (paragraph 5). Such oral composition has aluminum hydroxide as abrasives that permit the soluble aluminum compound to be stably incorporated in the composition and acts as analgesic and is used for prevention or remedy of dentinal hypersensitivity (paragraph 44). Aluminum hydroxide has a metallic and astringent taste in its soluble form and hence provides unpleasant feeling to the user (paragraph 62). The hydroxylalkylcellulose is used in combination with carrageenan and it improves the formability, syneresis, smoothness, stringing and stability of the composition. Moreover, it eliminates the slimy feeling and improves the good feeling in use and permits the soluble aluminum compound to be incorporated in the stable manner with minimum deactivation of effective aluminum ions (paragraph 47). Nakashima et. al also teaches that using hydroxylalkylcellulose alone may aggravate the formability and stringing of the composition and make the composition feel slimy and taste un pleasant, therefore, it is proved that carrageenan helps in reducing the astringent taste of the composition (paragraph 50). Nakashima et. al further mentions that the preferred carrageenan is .lambda.- carrageenan which improves the smoothness of the composition. The composition may contain certain amount of.iota.-carrageenan and .kappa.-carrageenan so long as they do not adversely affect the properties of .lambda.-carrageenan. The maximum permissible amount of .iota and .kappa.-carrageenen is about 50 % in the total carrageenan (paragraph 52). Nakashima

et. al also mention that sweetener such as sodium saccharin and mineral like potassium nitrate may also be added to the composition (paragraph 61 and example 14).

Thus the claims 1-3, 5-6, 11-14, 16-23, 28-31, 33-36, 44-47, 49 and 51 are anticipated by Nakasaki et. al.

## Response to Arguments

4. Applicant's arguments filed 06/15/2007 have been fully considered but they are not persuasive.

Applicant argues that "Nakashima et al. fails to teach or in any way disclose a composition as claimed by applicant, i.e. an orally administrable composition selected from the group consisting of foods, beverages, pharmaceuticals, nutriceutical and mixtures thereof. "

This argument is not persuasive because Nakashima teaches an oral composition for preventing and remedying dentinal hypersensitivity which comprises containing therein aluminum and a carboxylate compound (see abstract). Hence the prior art is directed towards a pharmaceutical preparation.

## *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3 and 5-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowry et al. (U.S. PGPUB 20010007878 A1) in view of Nakashima et. al. (U.S. Patent No. 4645662 A).

The teachings of Nakashima et. al. have been discussed above. Nakashima et. al. do not teach amino acids.

Lowry et. al teaches a nutritional product in a composition comprising L-arginine for a person having renal failure. L-arginine is found to be an essential amino acid in patients with renal failure because of the role it plays in the synthesis of endothelium- derived relaxing factor (summary of invention). The composition can be cow-milk based, soy-based, or based on other proteins or nutrients. Lowry et. al further suggest that the composition may also be administered via the normal oral route, and since the latter is preferred, the product's good taste is an important factor. Lowry et. al discloses that the nutritional product has moderate to high protein content and high calcium to phosphorus ratio. The composition contains vitamins and minerals and citric acid that is known in the art as flavoring agent and also water (paragraph 10, 14 and 16). The composition also typically contains emulsifiers and /or stabilizers such as carrageenan. (paragraph 25). Lowry et al. mentions that L-arginine is well known for it's

unpleasant taste and has detrimental effect of bitter elemental arginine on the taste of any formulation.

Although Lowry et. al disclose adding one or more carboxylic acids to provide good taste to the product but it does not teach utilizing carrageenan as a taste masking agent. However, in view of Nakasaki et. al , as discussed above, carrageenan can be used in terms of taste masking agent.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use carrageenan as suggested by Nakasaki et. al in making oral formulations of nutriceuticals containing amino acids as taught by Lowry et. al because carrageenan is noted upon to mask the metallic/bitter taste of amino acids. A skilled artisan would thus have been motivated to prepare better tasting oral formulations of nutriceuticals comprising amino acid, vitamins, minerals, flavorings agents and carrageenan with a reasonable expectation of success. It should be noted that while Lowry et al. and Nakasaki et. al do not explicitly teach the claimed concentrations and ratios of amino acid and carrageenan in the compositions and oral preparations of nutriceuticals as claimed in instant application, it is the examiners position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable ranges through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Further, in the absence of any unexpected results with respect to the claimed ratios and concentrations of the various components, it would have been obvious for the one of

ordinary skilled in the art to optimize the various components, in order to achieve the desired composition.

***Response to Arguments***

7. Applicant's arguments filed 06/15/2007 have been fully considered but they are not persuasive. Applicant argues:

"For reasons as stated herein above, Nakashima et al fails to teach or in anyway disclose a composition as now claimed by applicants. The examiner has suggested that Nakasaki et al teaches that carrageenan can be used as a taste masking agent. However, applicants' strongly disagree with the the Examiner's assertions. Clearly, Nakashima et al. discloses using carrageenan in combination with hydroxyalkylcellulose to improve the formability, syneresis, smoothness, stringing and stability of the composition. ( See Co. 5, lines 42). ..... Lowery et al reterence tails to teach or in any way suggested the use of carrageenan to mask the taste of the amino acid arginine. Conseqently, applicants' invention is unobvious over either of Lowery et al or Nakashima alone or in combination."

In response to Applicants arguments, Examiner points out that it is well established that the claims are given the broadest reasonable interpretation during examination.

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. in re Bozek, 163 USPQ 545 (CCPA 1969). The rational to modify or to

combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art.

In the instant case, in reference to the applied prior art, Nakashima discloses that hydroxylalkylcellulose is used in combination with carrageenan, it improves the formability, syneresis, smoothness, stringing and stability of the composition. Moreover, it eliminates the slimy feeling and improves the good feeling in use and permits the soluble aluminum compound to be incorporated in the stable manner with minimum deactivation of effective aluminum ions (see column 5, lines 41-45). Nakashima et.al also teaches that using hydroxylalkylcellulose alone may aggravate the formability and stringing of the composition and make the composition feel slimy and taste unpleasant (see column 5, lines 60-65). Therefore, it is proved that carrageenan helps in reducing the astringent taste of the composition. As such, it would have been obvious to the one of ordinary skilled in the art at the time of the invention to use carrageenan for improving astringent taste as motivated by the teachings of Nakashima et al. with a reasonable expectation of success.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached from 8:30 Am to 5:00 PM on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571)-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Snigdha Maewall

Art Unit 1615

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600